UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,283	03/13/2002	Susan B. Dillon	P50951	8717

20462 7590 04/21/2004

SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER	
TRAVERS, RUSSELL S	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,283	DILLON ET AL.	
	Examiner	Art Unit	
	Russell Travers, J.D.,Ph.D	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-25 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-25 are presented for examination.

The amendment filed January 5, 2004 has been received and entered into the file.

Applicant's arguments filed January 5, 2004 have been fully considered but they are not deemed to be persuasive

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required

undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that defines neither those compounds possessing CSBP/p38 inhibitor activity useful for treating those viral diseases herein envisioned, nor a method for ascertaining compounds possessing this activity absent an individual assay of compounds. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of those compounds possessing CSBP/p38 inhibitor activity useful for treating those viral diseases herein envisioned examples are set forth, thereby failing to provide sufficient working examples. Additionally, a method for ascertaining compounds possessing this activity, absent an individual assay of compounds, is not recited in the instant specification. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each

embodiment to be individually assessed for physiological activity. The instant claims read on all compounds possessing CSBP/p38 inhibitor activity useful for treating those viral diseases herein envisioned, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 1-13 and 18-22 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1-13, 18-22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-13 and 18-22 are rendered indefinite by the phrase " compounds possessing CSBP/p38 inhibitor" and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining medicaments that possess CSBP/p38 inhibitor activity are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Applicant's term fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims, 18, 21, 23 and 25 are rejected under 35 U.S.C. § 102(b) as being anticipated by Adams et al (644), in view of the Merck Manual (previously cited).

Applicants' attention is directed to the Merck Manual (page 1000) teaching the general incapacitating nature of influenza, and those complications herein envisioned as collateral to this malady. In the instant application supra, the claims are directed treating a disease with old and well known compounds or compositions. It is now well settled law that administering compounds inherently possessing this therapeutic utility provide relief for those effects collateral to this malady, as set forth in the Merck Manual. Well settled patent law charges the skilled artisan with the possession of that knowledge residing in texts on all subject matter recited in the instant claims. Thus, possessing the knowledge, this skilled artisan would understand the nature of those diseases herein treated, including those dangers herein recited as collateral to the influenza therapy herein claimed.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject

matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-7, 10, 14-16, 18, 21, 23-25 are rejected under 35 U.S.C. § 103 as being unpatentable over Adams et al patents, in view of Merck Manual(newly cited).

Adams et al teach the claimed compounds, and the penumbra of compounds encompassing those compounds, as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form ((048) pages 38 and 40, (644) column 12, lines 49-50, column 58, line 64, (499), column 28, lines 45-60, (992) column 1, line 54). These medicaments are taught as inhibitors of p38 and useful for treating viral disease and inflammation, to include viral respiratory diseases, and those symptoms collateral to viral diseases (see column 5, lines 35-49). Claims 7, 18, 21, 23 and 25, and the primary reference, differ as to:

1) the recitation of symptomatology collateral to viral infections, and

2) specific recitation of the compound recited in claims 15 and 24.

Applicants' attention is directed to the Merck Manual (pages 996-999) teaching the general dehabilitating nature of viral conditions, such as the common cold, and those complications herein envisioned as collateral to this malady. In the instant application supra, the claims are directed treating a disease with old and well known compounds or compositions. It is now well settled law that administering compounds inherently possessing a therapeutic utility provide relief for those effects collateral to this malady, as set forth in the Merck Manual. Well settled patent law charges the skilled artisan with the possession of that knowledge residing in texts directed to that subject matter recited in the instant claims. Thus, this skilled artisan would understand the nature of the claimed disease therapy herein provided as including therapy for those dangers herein recited as collateral to the antiviral therapy herein envisioned. Possessing these teachings the skilled artisan would have seen the employment of these compounds for treating viral respiratory diseases as obvious to the skilled artisan.

As stated above, Adams et al teach the claimed compounds, and the penumbra of compounds encompassing those compounds, as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for treating viral disease and inflammation, thus, encompassing the common cold, and those symptoms collateral to the common cold.

Claims 8, 9, 11, 12, 13, 19, 20 and 22 are rejected under 35 U.S.C. § 103 as being unpatentable over Adams et al patents, in view of Merck Manual, as set forth above for claims 1-7, 10, 14-16, 18 21, 23-25, in further view of the Wilkowski et al patents.

The Wilkowski et al patents teach the claimed compounds, and the penumbra of compounds encompassing those compounds, as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for treating viral disease and inflammation, to include those viral diseases herein envisioned, and those symptoms collateral to those viral diseases. Claims 8, 9, 11, 12, 13, 19, 20 and 22, and the primary reference, differ as to:

1) the concomitant employment of these medicaments.

It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional therapeutic agents. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Claim 17 is rejected under 35 U.S.C. § 103 as being unpatentable over Adams et al patents, in view of Merck Manual, as set forth above for claims 1-7, 10, 14-16, 18 21, 23-25, in further view of Bemis et al.

As stated above, Adams et al teach the claimed compounds, and the penumbra of compounds encompassing those compounds, as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form ((048) pages 38

and 40, (644) column 12, lines 49-50, column 58, line 64, (499), column 28, lines 45-60, (992) column 1, line 54). These medicaments are taught as inhibitors of p38 and useful for treating viral disease and inflammation, to include the common cold, and those symptoms collateral to the common cold. Claims 7, 18, 21, 23 and 25, and the Bemis et al reference, differ as to:

1) the recitation of a specific teaching of viral respiratory infections therapy.

Applicants' attention is directed to Bemis et al teaching the compounds recited in claim 17 as possessing p38 inhibition activity, general antiviral activity and as effective in treating fever. In the instant application, the claims are directed treating a disease with old and well known compounds or compositions. It is now well settled law that administering compounds inherently possessing this therapeutic utility provide relief for those effects collateral to this malady, as set forth in the Merck Manual. Well settled patent law charges the skilled artisan with possessing that general knowledge residing in texts disclosing that subject matter recited in the instant claims. Thus, this skilled artisan would understand the nature of the disease herein treated to include those dangers herein recited, and see therapy for such symptoms as collateral to viral infections generally, and viral respiratory diseases specifically, as herein envisioned. Thus, this skilled artisan would understand the nature of the disease herein treated included those dangers herein recited as collateral to general influenza therapy as herein envisioned. Possessing these teachings the skilled artisan would have seen the employment of the prior art compounds for treating viral respiratory diseases as obvious to the skilled artisan.

No claims are allowed.

RESPONSE TO ARGUMENTS

Those compounds recited in the presented claims are envisioned simply by their functional features, thus, placing the burden of ascertaining this functionality on those seeking to practice the invention. Absent specific recitation, this failure to provide guidance as to selecting the compounds useful for practicing the invention as envisioned, does not allow the skilled artisan to establish the metes and bounds for the claimed invention. As recited the instant claims read on all compounds possessing this function, discovered, and undiscovered. Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first paragraph. Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice

the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et* supra, at 468. Claims thus constructed provide no guidance as to medicaments employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection. Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention.

Newly presented obviousness rejections render the presented obviousness rejections moot. Examiner agrees the cited prior fails to teach treating the common cold. Attention is directed to Adams et al (column 5, lines 35-49) teaching the compounds herein envisioned as useful for treating inflammation collateral to vial infections. Although the prior art fails to recite the common cold, the skilled artisan would have seen the general anti-inflammatory teaching of Adams et al as encompassing the use herein recited, absent information to the contrary. The instant claims are directed to effecting a biochemical pathway with an old and well known compound. Arguments that Applicant's claims are not directed to the old and well known ultimate utility for this compound are not probative. It is well settled patent law that mode of action elucidation fails to impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over

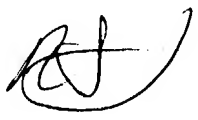
the prior art.". Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter, may in fact be an inherent characteristic of the prior art, it possesses the authority to requires the applicant to prove that the subject matter shown to be in the prior art dose not posses the characteristic relied on. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known, rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.
A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Travers, J.D.,Ph.D whose telephone number is 571-272-0631. The examiner can normally be reached on Monday to Thursday from 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-272-0631.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Russell Travers J.D., Ph.D.
Primary Examiner
Art Unit 1617